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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 31

Application Number: 09/100,100

MAILED

Filing Date: 06/19/98

DEC 16 2003

Appellant(s): James E. Ross, Jr.

GROUP 3600

Mark Joy

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/24/03.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

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The brief contains a statement that there are no other appeals and interferences that related to the instant application.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

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The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,701,400	AMADO	12-1997
5,764,923	TALLMAN et al.	01-1998

Collen, Morris F., *Hospital Computer System*, John Wiley & Sons, 1974, p. 94-104, 198-202.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 25-27, 37-39, 42-45, 51, 55, 56 and 62 are rejected under 35 U.S.C. 103 as being unpatentable over Amado (U.S. Patent No. 5,701,400) in view of Morris F. Collen (*Hospital Computer Systems*, 1974, Wiley and Sons, N.Y.) (hereafter Collen).

Claims 25 and 37: Amado discloses a method for rendering a report including medical language from previously stored data, said method comprising storing sentences and phrases related to medical data in peripheral CPU's, inputting patient data at a peripheral data input device, transferring the patient data from the peripheral data input device to a server communicatively coupled to the peripheral data input device and tabling the patient data at the server, transferring the tabled patient data from the server to a report rendering component, and compiling sentences and paragraphs by the

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report rendering component from the stored sentences and phrases and the patient data, whereby stored medical facts associated with the input data are converted into sentence structure (Col. 1, lines 31-41, col. 20, lines 16-63, col. 24, lines 45-67). However, Amado does not explicitly disclose creating structured medical reports and stored sentences and phrases. Collen discloses such steps.(Page 199, line 17-page 202, line 27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include such steps. One would have been motivated to do that in order to increase the facility to enter and retrieval information stored in the system.

Claims 26 and 38: Amado and Collen disclose the method of claims 25 and 37. Amado also discloses rearranging the medical facts compiled into the sentence structure into a medically appropriate order (Col. 24, lines 5-42 and Abstract).

Claims 27 and 39: Amado and Collen disclose the method of claims 26 and 38. Amado also discloses consolidating, by the report rendering component, automatically generated medical English text with patient-related stored text and generated medical text with patient-related stored text including dictated transcripts (Col. 26, lines 33-55).

Claims 42 and 55: Amado discloses a method and a system for computer-aided generation of patient medical documentation assembled from a combination of sources including user supplied text, information retrieval system from a database in accordance with a specified pre-phrased text identifier, and text generated from input medical data facts, said method comprising the steps of:

associating multiple pieces of information regarding a patient with a patient medical information record, the multiple pieces of medical information, comprising:

input text of the type generally arising from transcribed dictation,
retrieval information system for texts from an electronic data storage apparatus and
associated with a pre-phrased text identifier, and
medical data facts (Col. 29, line 42-col. 30, line 53),

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wherein inputs relating to the multiple pieces of information regarding the patient are received by a medical information input interface providing random access to at least one of a set of medical information fields associated with the patient medical information record, receiving an identification of a patient medical document type; and generating, by a computer system under software control, a patient medical document based upon ~~at least a portion of the multiple pieces of information regarding the patient and an information specification corresponding to the patient medical document type identification that specifies the portion of the multiple pieces of information to be included in the patient medical document, said generating step comprising, in any order:~~

first inserting the input text at locations within the patient medical document in accordance with a text type associated with each distinguished portion of the input text (Col. 30, line 55-col. 31, line 67),

second inserting text corresponding to the pre-phrased text retrieved from an electronic data storage apparatus (Col. 32, line 49-col. 33, line 15), and

third inserting text generated in accordance with the medical data facts (Col. 51, line 1-col. 54, line 58).

However, Amado does not explicitly disclose the use of pre-phrased text retrieval and pre-phrased text identifier in his information system retrieval. Collen discloses such steps.(Page 199, line 17-page 202, line 27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include such steps. One would have been motivated to do that in order to increase the facility to enter and retrieval information stored in the system.

Claim 43: Amado and Collen disclose a method of claim 42. Amado also discloses wherein the text generated in accordance with the medical data facts is generated in accordance with a medically logical sequence (Col. 32, lines 1-59, col. 53, line 30-col. 58, line 54, and col. 61, line 21-col. 63, line 9).

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Claim 44: Amado and Collen disclose a method of claim 42. Amado also discloses wherein the step of generating a patient medical document further comprises generating heading text in accordance with the patient medical document type designation (Col. 70, line 59-col. 72, line 27, and col. 76, line 32-col. 77, line 57).

Claims 45 and 56: Amado and Collen disclose a method and a system of claims 42 and 55. Amado also discloses wherein the step of generating a patient medical document further comprises arranging the multiple pieces of information regarding the patient in accordance with the medical document type designation (Col. 32, line 1-col. 33, line 44, col. 35, line 24-col. 39, line 30).

Claim 51 and 62: Amado and Collen disclose a method and a system of claims 42 and 55. Amado also discloses providing a set of selectively activated input modules facilitating prompted input of information relating to care for a patient (Col. 34, line 56-col. 35, line 22).

3. Claims 28, 29, 40, 41, 46, 48-50, 52-54, 57, 59-61 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amado (U.S. Patent No. 5,701,400) in view of Collen.

Claims 28, 29, 40 and 41: Amado and Collen disclose the method of claims 27, 39 and 41. However, the references do not disclose the step of inserting, by the report rendering component, headlines and sub headlines with the report, nor modifying, in accordance with programmed report generation instructions, the fond of text within particular portions of the report to use of bold, italic, and larger text sizes to emphasize important medical sections or information. Official notice is taken that those steps are well known within the art to emphasize important information. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use these steps to emphasize important information. One would have been motivated to use this procedure in order to facilitate the reading of the patient medical document and to saving time in the medical decision process making.

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Claims 46, 48, 49, 57, 59 and 60: Amado and Collen disclose the method and system of claims 42, 45, 55 and 56. However, the references do not disclose that when the patient medical document is a patient medical report or the nurse notes that the text generated is medical text. Official notice is taken that those steps are well known within the art and are currently used in the day to day management and updating of patient records. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use these steps to update the patient records. One would have been motivated to use this procedure in order to include inputs about the patient status from different professionals, with different relevance throughout the entire day.

Claims 50 and 61: Amado and Collen disclose the method and system of claims 42 and 55. However, the references do not disclose the step of providing an editing tool to modify specified pre-phrased text. Official notice is taken that this step is well known within the art and is currently used in the text processing art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use that step to modify specified pre-phrased text. One would have been motivated to include modifying specified pre-phrased text in order to increase the flexibility in the text processing.

Claims 52- 54 and 63- 65: Amado and Collen disclose the method and system of claims 42 and 55. However, the references do not disclose the steps of providing a security mechanism facilitating limiting access to particular users, recording a time at which a particular piece of information is submitted for a patient medical record, nor recording an identity of a logged on user that supplied a particular piece of information stored in the patient medical information record. Official notice is taken that those steps are well known within the art and are currently used in the security data processing. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use these steps to guarantee the patient's privacy. One would have been motivated to use this security procedures in order to minimize the risk of inappropriate diffusion of personal data.

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4. Claims 47 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amado (U.S. Patent No. 5,701,400) in view of Collen, and further view of Tallman et al. (U.S. Patent No. 5,764,923).

Amado and Collen disclose the method and system of claims 45 and 56. However, the references do not explicitly disclose wherein the patient medical document is a triage record. Tallman discloses such as step (Col. 11, lines 29-34). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that one type of patient medical document could include a triage record. One would have been motivated to include a triage record as the patient medical document in order to include all pertinent data in the case to provide the files support for diagnosis and therapeutic decisions.

(11) Response to Argument

This answer is focused on the most relevant arguments of the appeal: issues regarding groups I, II, and III.

Group I (Claims 25-27, 37-39, 42-45, 51, 55, 56, and 62)

Appellant states: "Amado, in no way, discloses anything having to do with medical data report generation." (Page 7, line 12).

Examiner notes that Amado discloses: "Diagnosis and classification expert systems select an answer from a fixed set of alternatives on the basis of information input to the system while it is reasoning. For example, the MYCIN.TM expert system by Stanford University of Stanford, Calif. diagnoses bacterial infections in humans. Another diagnosis and classification expert system, the MUDMAN TM expert system diagnoses problems with "Mud" used in NL Baroid's oil well drilling and recommends new compositions" (Col. 3, lines 20-28) (emphasis added).

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Moreover, Amado discloses: "Debugging and repair systems specify remedial plans and apply them in limited areas. Computer programming is the most obvious area of application , but medical diagnostic systems also have debugging aspects." (Col. 4, lines 44-47) (emphasis added).

Furthermore, Amado discloses: "Neural nets are tools that attempt to mimic the human brain by "learning" different sets of stimulus patterns (such as medical symptoms) and their associated responses (diagnoses)." (Col. 6, lines 65-68) (emphasis added).

Thus, Amado discloses diagnostics also in the medical field.

In addition, Amado's invention refers in multiple occasions to reports and displays that show the results of the diagnoses, e.g.:

Brief Summary Text (5):

"Current software implementations do not address directly the need for a system integrating (a) report analysis via an EIS system incorporating the generation of diagnostics using a combination of artificial intelligence techniques, (b) storage of said diagnostics in a database related to the original information in the reports, and (c) a query system, empowering the user to search for any information in both reports and diagnostics in a coordinated manner." (emphasis added).

Brief Summary Text (8):

"...existing tools do not address the specific functionality of this invention. These systems allow managers to see very simple summary reports from huge amounts of information stored in databases. In other words, EIS are tools allowing programmers to build simple reporting applications for managers. A few tools will be now discussed as good examples of the current state of prior art." (emphasis added).

Brief Summary Text (12):

"The Corporate Vision.TM. decision support tool by IntelligenceWare Inc. of Los Angeles Calif. is a spreadsheet program that helps user visually analyze facts and graphically see corporate data. Merges

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data from several sources, filters and extracts facts and provides user with key information on demand.

Displays information in 3D graphics, tables and hypertext in exchangeable format." (emphasis added).

Brief Summary Text (13):

"The Iconic Query.TM. decision support tool by IntelligenceWare Inc. of Los Angeles Calif. is a graphical query tool which allows users to visually create queries on-screen. Supports graphics, reporting features and query capabilities. Replaces query language used by developers with icons to get information from databases. Includes Paradox and dBase drivers. Provides support for hypertext help and ability to incorporate 3D graphics into applications. Includes WYSIWYG reporting and label generation." (emphasis added).

Brief Summary Text (14):

"The Intellect.TM. decision support system by AICorp Inc. (now Trinziec) of Waltham Mass. is an AI-based natural language system allowing management access to production databases for English language query, ad hoc analysis, report formatting and database updates. Generates presentation-quality graphs or downloads data to PC. Intellect 400 provides simultaneous multiple database access and supports IBM mainframe databases and 4GL systems including DB2, SQL/DS, IMS, IDMS, ADABAS and Focus. Operates standalone or integrates with AICorp's KBMS." (emphasis added).

Brief Summary Text (18):

"Expert Systems are computer programs that capture human expertise in problem solving in a small area, to provide automatic solutions to similar problems. Usually, these are written in a set of if/then rules, called a rule base or knowledge base. Expert systems building tools typically consist of (a) an interpretive language where the user may write his or her program statements and the conditions associated with those statements, (b) an inference engine, which provides the mechanism through which the expert rules are interpreted and fired, and © an executive front-end or expert shell, that helps

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users write application programs using the language, and that helps them run the expert applications developed, and that also helps them develop and query reports or the generated diagnostics." (emphasis added).

Brief Summary Text (20):

"Expert systems are a specialized subset of DSSs (decision-support-systems) that employ symbolic reasoning to manipulate data and produce reports. If the judgment employed by the users is procedural in nature (i.e., requires a set number of steps to reach a predetermined conclusion), then a conventional DSS should be developed. However, if the user reaches a conclusion based on a variety of factors that cannot be captured using an algorithm, then an expert system could be developed." (emphasis added).

Brief Summary Text (26):

"(v) Monitoring expert systems obtain data on an ongoing situation following its predicted or intended progress and alerting the user or system if there is a departure from the expected or usual. Expert systems capable of monitoring their environments compare observations to desired outcomes and report discrepancies. They must recognize alarm conditions in real time and avoid false reports of problems or emergencies. Note that "real time" expert systems are significantly different than those which allow the luxury of reflection. Because of varying environmental factors, monitoring systems must vary their anticipation of alarm conditions with time and situation. Air traffic control and nuclear power plant management are two current fields of application. Additionally, NASA's NAVEX monitors controls on space shuttle flights." (emphasis added).

Brief Summary Text (58):

"The Neuralyst for Windows.™ neural network tool by Epic Systems Corp of Sierra Madre Calif. is a general-purpose neural network engine with Microsoft Excel integration. Provides self-programming neural network. Allows user to act as coach by providing data and setting goals for program to learn.

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Reports continuously on performance. Allows user to develop expert systems, pattern recognizes, outcome predictors and risk evaluators. Uses Excel macros." (emphasis added).

Brief Summary Text (90):

"In "Intelligent databases and object-oriented languages," Computer Language, October 1989 v6 n10 p67(8), Mark H. Chignell discusses the integration of expert systems and databases within an object-oriented framework. Such integration is appealing because the user can directly manipulate the database's semantics. In such an intelligent database system, expert rules dealing with data can be programmed in the same environment without using any external expert system tool. Ordinary database applications (such as data entry and report and application generation) and intelligent processing of data can be mixed." (emphasis added).

Brief Summary Text (93):

"The overall architecture of a logic database application includes at least the following components: logic database application program, data model stored in an active data dictionary, database access and storage, rule base (and knowledge network) access and storage, inference engine, user dialogue input, database transactions, and screens and reports." (emphasis added).

Brief Summary Text (103):

"Thus, it can be concluded that intelligent databases represent a collection of tools that altogether help users better understand and visualize their data. These tools are usually knowledge extraction tools as described elsewhere in this document, graphic query systems, and embedded executive information and reporting systems. Object-oriented databases development tools employ object-oriented techniques to substitute the fields, records and pointers scheme of relational databases with a far more flexible approach of definable classes of objects with inheritance. Where database dictionaries in relational databases show a regular structure, those dictionaries of object-oriented databases closely follow the object database structure. This allows the development of expert and artificial intelligent systems within

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object databases, simply associating expert rules and specific algorithms to particular elements in the dictionaries. Intelligent databases can help us make discoveries automatically." (emphasis added).

Brief Summary Text (112):

"Links are between nodes. Some link types that provide the basic functionality required for intelligent databases are: (ii) Pan links move to a related node. They allow one to move around or navigate through hypermedia. (ii) Zoom-in links expand the current node into a more detailed account of the information. Zoom-out links return to a higher-level view of the current object. (These links are particularly useful in browsing facilities.) (iii) Hierarchy links allow the user to view any hierarchies in which the current object is embedded. If more than one hierarchy is involved, the user chooses the appropriate context. (iv) Broaden links display the parents of the current object for the hierarchies it is embedded within. Specialize links display the children of the current object as defined by the hierarchies in which it is embedded. (v) Conditional links. The availability or activation of these links depends on the stated interests or purposes of the user. Conditional links are hidden unless of interest or a particular user has access to them. (vi) Index links move the user from an indexed node to the corresponding index entry for that node. The index can be used to enter the relational database or to find documents sharing a particular index term. Indexing hypertext is a good way of controlling the proliferation of links between nodes." (emphasis added).

Brief Summary Text (135):

"The Acquire.TM knowledge extraction tool by Acquired Intelligence Inc. of Victoria BC, Canada, is a Knowledge-based system. It provides a structured approach to knowledge acquisition. It helps the user to scope the problem, decompose the problem, elicit and structure expertise, identify meaningful patterns in the knowledge, identify the consequences of those patterns, and deal with uncertainty and ensure completeness. Using this system, people with domain knowledge can build significant knowledge-based systems. Guides knowledge acquisition throughout the development of a

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knowledge-based system including the critical, upfront task of acquiring and structuring the knowledge. The person is led through the task of eliciting and structuring the expertise, then through the development of an operational model of that expertise implemented in the program's representation, ready for testing and refinement. The person with the domain knowledge is given complete control over the development of the system. This program handles knowledge engineering. Implements a model of knowledge acquisition based on pattern recognition. Handles uncertainty by qualitative, non-numerical procedures. Provides the structure of the knowledge in graphic displays for browsing. Incorporates machine learning techniques. Represents knowledge as objects, production rules and decision tables. Provides an explanation and an exploration of what the system is doing and why. Provides reports for a wide variety of uses, from working messages to detailed reports informal documents." (emphasis added).

Brief Summary Text (139):

"The ExploreNet 3000.™. knowledge extraction tool by HNC Inc. of San Diego Calif. provides development and delivery of neural network applications. Includes data transformation, file, pipe, display and network modules." (emphasis added).

Brief Summary Text (142):

"Database Visualization Tool.™. (DVT.™.) knowledge extraction tool by IntelligenceWare Inc. of Los Angeles Calif. contains algorithm that evaluates data and suggests graph types that best illustrate database. Offers variety of graph and chart types including 2D line graphs, histograms, pie charts, bar charts, box plots and surface diagrams. Allows user to display numeric and non-numeric information. Includes 3D box graph which illustrates all of company's ongoing projects. " (emphasis added).

Brief Summary Text (143):

"The Information Discovery System.™. (IDIS.™.) knowledge extraction tool by IntelligenceWare Inc. of Los Angeles Calif. analyzes databases, automatically generates hypotheses, discovers hidden and

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unexpected patterns, rules of knowledge, graphs and anomalies. Displays results within hypermedia environment. Combines automated data analysis, graphics, statistics, induction and hypermedia. Analyzes data without requiring user to formulate and test hypotheses. Formulates questions, executes them and collects data." (emphasis added).

Brief Summary Text (145):

"The DataLogic™ knowledge extraction tool by REDUCT Systems Inc. of Regina, SK, Canada, is a tool to reason from data, a professional tool for knowledge acquisition, classification, predictive modeling, expert systems building, and database "mining". This product is a decision support and database mining software that provides data analysis and knowledge discovery based on the methodology of rough sets. It analyzes logical patterns in data, including theories of knowledge representation, inductive logic and rough sets. It provides forecasting and decision making from imprecise, incomplete and ambiguous data. It discovers simple knowledge rules from data and provides full auditability of rules and decisions. With the Missing Data Module, the program can also process incomplete databases without filling in missing values. It generates rules at different levels of knowledge representation and rule precision. It provides several reports. The Rule Report describes significant logical patterns/rules in the database. The Rule Support Report describes pattern strength, and data which support the patterns. The Validation Report describes accuracy of the uncovered patterns and rules. The Expert Report describes recommended decisions for new cases, and the Decision Report describes how decisions were made." (emphasis added).

Brief Summary Text (146):

"The DataQuest.™. knowledge extraction tool by REDUCT Systems Inc. of Regina, SK, Canada, data analysis software package based on the theory of rough sets and is used as an introductory learning tool for this methodology. Designed for business, industry and research, this product assists user in learning and understanding basic concepts of rough sets. This product uncovers logical patterns in data

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and predicts outcomes of new cases. It performs logical analyses of user's databases and provides user with expert rules for decision making. It uses logic to recognize patterns in data and can discover knowledge which is inaccessible to statistical methods. The analysis does not require information on data distribution and can be performed on incomplete and/or limited data. It measures data dependencies and significance of variables. It provides selection of data fields for analysis, elimination of irrelevant information, and prediction of outcomes for new cases. Its results can be saved in a report, including rules generated from the data, list of variable subsets and the quality of these subsets for data analysis, and measures of data dependencies and attribute significance." (emphasis added).

Brief Summary Text (151):

"Management information systems do not typically have symbolic reasoning capabilities. The graphic displays are static in the sense that there is no [explanation] or interpretation facility. The user must know how to format queries; the system cannot reformat queries if the user is not sufficiently specific. Vague or uncertain information contained in a management information system query may result in computer resource intensive processing caused by extensive database [searches]).

Brief Summary Text (166):

"Experienced managers receive a continual stream of information and analyze it almost by instinct. They wade through standardized reports, select relevant information, compare numbers from different sources, estimate a number of indexes and finally generate conclusions." (emphasis added).

Brief Summary Text (167):

"Other spreadsheets or executive information systems produce financial ratios and reports, and some provide simple interpretations of these indexes. The invention adds extra power and agility because it offers sophisticated advice in very flexible formats and lets you easily adjust the criteria for making these recommendations. The invention gives users the tools to create and analyze specific expert diagnostics in a straightforward manner." (emphasis added).

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Brief Summary Text (171):

"The invention lets managers concentrate in action and strategy, that is, in their final goals and results. It executes all repetitive report analysis, ratios and number comparisons, signals for dangers, menaces, strengths and opportunities. With other state-of-the-art technologies, data integration has meant easy access to all data. All this translates to data accumulation and proliferation, and makes data handling ever more complicated. ~~The invention immediately shows priorities according to the managers' own needs, preferences and criteria. The invention enhances current executive information systems (EIS) and data analysis technologies, helping managers determine which information they should review.~~" (emphasis added).

Brief Summary Text (174):

"The invention is a simple tool to use. It incorporates downdrilling techniques to navigate through the data. It is flexible and customizable: it lets the user develop tailored Expert System applications easily. Analytical criteria may be added or modified instantly and it does not require expert programmers because it incorporates a 4GL interface. The user can easily browse through the data and develop menus, reports, graphs and help screens." (emphasis added).

Brief Summary Text (179):

"Third Sample Application: Quality control at a Consulting Firm. Supervision at a consulting services division with more than a thousand clients and specialized attention to two hundred clients on a daily basis. Expertto is capable of generating detailed and annotated quality control reports for each case and client, by condition and type of problem, responsible person, department or service." (emphasis added).

Brief Summary Text (201):

"The invention combines an EIS building tool and expert system building tools with database management instruments (a) applying expert knowledge to any information contained in databases and

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reports, (b) linking the expert system results, hereby called diagnostics, with selected related data on the databases and reports, as defined by the user, and (c) presenting a query interface capable of structuring and showing the resulting diagnostics and the original linked data according to user preferences such as actions and priorities." (emphasis added).

Brief Summary Text (205):

"The invention also incorporates a fast-development graphical EIS with downdrilling tools. This is really an AI/Enhanced EIS, because these graphical reports may simultaneously show diagnostics and data." (emphasis added).

Brief Summary Text (222):

"The invention is different from existing diagnostic EIS tools. Typical prior art EIS diagnostics tools such as the Analyst.™. decision-support software by Information Resources Inc. of Waltham Mass. displaying output contain "hyperlinked" slide shows of ordinary presentation screens containing graphic reports of the data (numbers and graphics). However, the user may associate particular logic tests to certain data items. If a logical test runs TRUE, then a message shows next to the corresponding data item. These systems perform all logical tests "on the fly". That is, whenever a particular screen is called, the information is first read, then interpreted, then the logical test or tests are run and the screen is built altogether. There are no databases for storing any diagnostics, there are no links, and there is no mapping process. Each diagnostic is generated one-at-a-time." (emphasis added).

Brief Summary Text (277):

"The invention has been implemented under different operating system environments. In the Microsoft Windows.™. implementation, developed using the Microsoft FoxPro.™. program development tool by Microsoft Corporation of Redmond, Wash., it easily integrates with Microsoft Windows.™. Spreadsheets like the Microsoft Excel.™. spreadsheet by Microsoft Corporation of Redmond, Wash. Toolbars such as

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the one shown in FIG. 33 allow users to easily operate the system menus, graphical action buttons (EIS), activate help options, user notes, summary reports, graphics, etc." (emphasis added).

Drawing Description Text (13):

"FIG. 9 shows the overall flow diagram of the best embodiment's implementation: FIRST, the invention must access all the firm's databases (see 1 to 4 in FIG. 1) to build the data database (5). SECOND, the invention generates a complete database structure and related index files (16). The just-generated test and diagnostic database files (7) are empty, but ready to receive information. The detailed database structure, index files contents and relations between the files will be made evident in the next Figures of this application. THIRD, define any groups (14, 15) of data items (12). THIS IS OPTIONAL. These groups are useful for the application of common tests to all data items in any particular group, for the definition of reports and queries, and for the definition of the associated triggers and actions (23, 24). FOURTH, define tests (17, 18, 19) and formulas (20, 21, 22). Formulas can be as simple as IF-THEN tests applied to one or more data items or data groups, or as sophisticated as expert system clauses and rules, neural networks and genetic algorithms can be. FIFTH, apply formulas. The test-processing engine (10) then interprets and executes all formulas, reading and comparing all relevant data items, and whenever a test's conditions turn TRUE, generating one or more diagnostic records in the diagnostics database (7). Any diagnostic reference stored in the diagnostic database will also contain an associated reference to one or more data items (12). These data items will be defined by the user, or they will simply be the data items examined when the test condition turned true and the ensuing diagnostic was generated. SIXTH, query the application. The user may query the diagnostics database and the data database simultaneously in two or more separate windows, linked through several index files (16)." (emphasis added).

Drawing Description Text (14):

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"FIG. 10 shows the steps required to use and query an application: (a) Select the desired application. Use command File--Open Application. (b) Observe selected tables (optional). Observe selected tables from the application's database (5+7+9). This is optional. The user will do it only if he/she wants to. © Browse the expert diagnostics. Use command View--Diagnostics. Observe or browse the expert diagnostics, for example, to understand the general condition of the firm. (d) Browse the action categories. Use command View--Action Categories. Observe or browse the diagnostic frequencies classified by appropriate triggers and actions, according to the user preferences. Observe or browse the diagnostics trying different trigger and action combinations (action1, action2, action3, action4, action5) to identify the original data related to key diagnostics. (e) Browse the data and diagnostics. Use command View--Data. Observe or browse the original data for a final review, since this is the option closest to traditional report-analysis methods. (g) Select another application (optional). Use command File--Open Application. The view steps outlined above may be executed in any order, together with View EIS, to look at the data and diagnostic in the typical graphical mode of an Executive Information System." (emphasis added).

Drawing Description Text (57):

"When querying an application, as shown in FIG. 48, the invention includes a user-friendly EIS interface which allows the user to generate reports, create eye-catching graphics, and develop customized help screens so that others in the organization can use and understand these applications. FIG. 48 shows the initial screen for a sample EIS application." (emphasis added).

Drawing Description Text (59):

"FIG. 50 shows another sample screen of the EIS querying tool enhanced by the diagnostics in the diagnostics database. This also shows a highlighted graph. If the user double-clicks at any particular graph, the invention will show another screen, containing more information related to that particular graph. The invention incorporates downdrilling techniques to navigate through the user's data. While

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looking at any screen, simply point at the desired graph and a more detailed report relating to the corresponding data will instantly appear on the monitor." (emphasis added).

Drawing Description Text (65):

"FIG. 56 shows another way to display the user's information. The user may keep creating continuously new ways to look at the user's data and their associated diagnostics. " (emphasis added).

Drawing Description Text (140):

"FIG. 127 shows a typical report generated by a "corrective management system": profits and number of defects for four business divisions for the previous and current periods, and the increment (decrement) in these numbers." (emphasis added).

Thus, from the above quotations, Amado discloses reports, graphics, and displays, which refers to the medical field as discussed in the initial point of this paragraph.

Referent to Collen's teaching:

Collen disclosed storing sentences and phrases related to medical data, inputting patient data, transferring the patient data to a server that tables the patient data, transferring the patient data to a report rendering component, and compiling sentences and paragraphs, by the report rendering component, from the stored sentences and phrases and the tabled patient data, as the below quotations.

Collen, in his 1974 book *Hospital Information Systems* includes a paper of Douglas A. Williams, which discloses:

"... a patient's appointment schedule, advance schedule of patients by doctor or clinic which can be used to evaluate physician patient load, and identification of high utilization patterns for special

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review. Backup procedures are employed, using appointment schedule printouts to locate available openings until the system is functioning properly; any booked appointments are then entered to update the computer appointment schedule files. The automated system requires one minute to confirm an existing appointment, two minutes to schedule an appointment, and three minute to cancel an appointment." (Page 94, lines 2-10).

Examiner cited this Colten paragraph to situate the application into the framework of the medical automatization applications. These type of applications started many years before the publication of the Collen's book. In fact, Collen teaches:

"A significant application of computers and data processing has developed over the past ten years in the field of abstracting and reporting medical records. Two basic hospital reporting requirements are included: the recording of various routine statistics such as admission /discharges, patient days by type of service, length of stay, etc., and case abstracts for discharged patients indexed by diagnosis, operation, and physician. The information contained in these reports can be used to satisfy hospital accreditation requirements and provide information required by local or state officials, for medical audits by the professional staff of the hospital, for staff education and research programs, and, finally, for hospital management and planning." (Page 94, lines 20-30).

Storing information on the patient using codes is old and well known for the experts of computers applied to the health field, as Collen wrote:

"The first computerized system for compiling hospital reports was developed in 1952 by Slee and associates from the Southwestern Michigan Hospital Council. [Slee, Vergil N., M.D., "Measuring Hospital Effectiveness: Patterns in Medical Practice." *The University of Michigan Medical Center Journal*, 35 (1969):112]. A standardized case abstract form containing basic information about the patient, coded information identifying hospital and physicians, and provisions for recording multiple diagnosis and procedures related to the patient's hospitalization was developed. Beginning its first

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operation in early 1953 with a group of 13 participating Michigan hospitals, the system was so successful that, by 1955, an independent nonprofit corporation, the Commission on Professional and Hospital Activities, was formed with the support of the American College of Physicians, American College of Surgeons, the American Hospital Association, and a private foundation. The system, now known as the Professional Activity Study (PAS), has experienced steady growth from its inception; at the end of 1971, there were 1,560 hospital participating in this shared computer service [Re.: Kinkaid, WillimH. Editor, "PAS Reporter." *Commission on Professional and Hospital Activities* 10 (2972)]. These hospitals account for over 12 million abstracts annually. During the past decade, the PAS system has processed over 60 million abstracts and thus represents the largest single resource for computer-stored medical record information in existence. Over 70% of the PAS member hospitals also participate in a supplementary program, the Medical Audit Program (NIAP). The MAP reports, prepared quarterly, utilize the same basic case: abstract prepared for PAS; however, more elaborate and detailed information is reported for use by the professional staff in performing internal medical audits. This activity is discussed in more detail by Slee [Slee, Vergil N. M.D., "The Medical Audit", *Hospital Progress*, 46 (1965):106-108] and Williams [Williams, Kenneth J., M.D., "Practical Applications of the Medical Audit, *Hospital Progress*, 46 (1965):109-111]. A separate development in the field of hospital medical record reporting was initiated by the California State Department of Public Health. Known as the CHIPS project (California Health Information for Planning Services), a series of 12 computer produced report; were designed in 1966 and implemented by three hospitals in early 1967. As reported by Derry, et al., "the project has several objectives: to provide comprehensive institutional reports for use by professional and hospital management; to compile area planning reports for better planning of health care facilities in the State; and to support a health information exchange through which participating agencies could benefit through improved information relating to health services, manpower, and community planning. In December 1967, California Health Data Corporation (CHDC) was formed as a nonprofit organization to

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establish a health information exchange. Supported by the California Medical Association, California Hospital Association, and the CHIPS advisory group, CHDC continued the development of medical record reporting programs which presently support over 200 California subscriber hospitals. Both the PAS and CHDC systems charge their member hospitals between 30 and 40 cents per abstract for the standard series of reports produced. Additional income is derived from special research studies utilizing these information data bases. (Page 94, line 31-page 95, line 35).

And the paper described the "COMMERCIALLY DEVELOPED HOSPITAL COMPUTER SYSTEMS" at that time:

"As the information processing needs of the hospital (estimated to range anywhere from 25% to 40% of operating costs) were recognized, there followed the development of several general purpose computer systems for the hospital. These evolutionary developments are characterized by a diversity of systems approaches, which include: (1) general administrative software for use by the hospital on its computer system; (2) ability of hospital applications through communications terminals to a shared hospital service bureau; (3) dedicated hospital computer oriented to more comprehensive order entry and information retrieval capabilities; and (4) contractual arrangements among several hospital to develop user-tailored or customized systems. Several of the commercially developed hospital computer systems are briefly described. Each systems approach offers certain advantages and disadvantages; all require careful study and evaluation by the prospective hospital user whose particular requirements and needs should be defined in detail before selection of any system is anticipated.

1. MISP/SHAS

IBM has devoted major resources in their research and development efforts relating to computer systems for the hospital and medical applications. By the mid-1960's, IBM was developing the Medical Information Systems Programs (MISP) in cooperation with Monmouth Medical Centerter. MISP is a series of executive and control programs which perform various functions including terminal polling and

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line control, data management, general system control, and user application program initiation.

Implemented in late 1967, MISP has been improved upon and adopted by more than 24 hospitals. Most of the application programs developed by MIISP user hospitals (e.g., admitting/bed census) have been shared by others through a user-group organization. IBM evolved their hospital applications program through a series of developments leading to the Shared Hospital Accounting System (SHAS). The SHAS system supports a supervisory control and teleprocessing executive program which provides for a shared centralized computer facility available to several hospitals through telephone communications and remote terminals. SHAS offers application programs in the areas of patient billing (both inpatient and outpatient), accounts receivable, and general ledger. A number of features are available to user hospitals to provide for customing of SHAS applications to meet specific needs or standard practices for each shared hospital. These include patient identification procedures; report format controls; Medicare reporting options; selective printing and scheduling of reports; insurance proration; and a hospital profile feature which provides SHAS with information on hospital name and address, accounts receivable parameters, census summary data requirements, and control parameters for hospital billing procedures. The SHAS application subsystems are oriented to hospital management. The patient billing subsystem processes patient accounts from readmission to final billing; a number of related data files are updated and maintained throughout the patient's hospital stay, providing for charge collection, pricing, patient account inquiry, and billing (with provision for insurance proration and Medicare invoicing). A census subsystem provides various reports on preadmissions/admissions/discharges/ transfers, and census summary reports by nursing station, service, and doctor. Another byproduct of the billing subsystem is the reporting of management statistics regarding hospital census, percent of occupancy and days of care by service. The accounts receivable subsystem operates in conjunction with the patient billing application by accepting the final billing at the time of patient discharge and maintaining the accounts receivable until the account is closed. This subsystem provides for recording of payments from the

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patient of third party (Medicare, insurance, etc.), accounts receivable inquiry, and management of accounts (bad debt write-off, statement consolidation by family, statement cycle billing). A series of reports provide for aged trial balance, insurance accounts receivable, delinquent accounts, bad debt write-off, current account status, and several cross-indexed directories. The accounts receivable subsystem also produces entries to the third SHAS subsystem application, the general ledger. The general ledger application provides a series of financial reports to hospital management. A daily process accepts transactions from both the patient billing and accounts receivable subsystems as well as other user-provided application programs (e.g., cash disbursements, payroll, purchasing) and posts these entries to a general ledger file. The reporting programs produce a variety of accounting and financial journals, trial balance, operating statements, balance sheet, and cost allocation summary. SHAS was first implemented at the Loyola University Hospital and has since been adopted by more than 100 hospitals. This system combines both remote terminal communications between the hospital and the SHAS central computer and batch processing of the more voluminous reports on a scheduled basis. The user can provide for alternative choices of terminal device types including typewriter, card reader, and line printer.

2. MEDINET

MEDINET is the designation given to an autonomous section of the Information Services Business Division of the General Electric Company. After a two-year study of hospital information systems needs, MEDINET adopted a general approach termed "cycle processing," which combine on-line computer processing with off-line batch processing methods. The MEDINET system was designed as a general purpose, shared-hospital service bureau operation with subscriber hospitals contracting for various application services. MEDINET operations began in August 1968, and the system presently services a number of hospitals from Maine to Florida. Early emphasis was placed on application programs to serve the need of hospital management. These include the areas of census and utilization

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patient billing, personnel accounting, accounts receivable/payable, and general ledger.

MEDINET provides for four distinct modes of operation; subscriber hospitals can select from these in meeting their particular needs. In the *Communications Processing* mode, MEDINET terminals can be located throughout the hospital providing direct communication between departments. A communications computer processes and routes message traffic in addition to collecting data for subsequent applications processing. A second mode is *Remote Entry Batch with Cycle Processing*. Using leased telephone lines and appropriate terminal devices, the subscriber hospital enters daily operating data; on a scheduled basis, MEDINET application programs process this data and produce reports which can be transmitted back to the hospital or, if not time-critical, printed at a MEDINET site for subsequent delivery to the hospital. A third mode is *Batch Processing*, in which input data is keypunched and processed by MEDINET in application areas not requiring rapid service (e.g., medical record statistics). Finally, a fourth mode, *Tinze-Sharing*, provides for sophisticated application developments using real-time terminal communication between the subscriber hospital and a series of MEDINET application programs in such areas as cash flow analysis, budget analysis, nurse/staff allocation, and cost allocation. This mode also provides the means for developing specific user application programs utilizing the MEDINET software system. A five-phase approach is used by MEDINET to implement an application for a subscriber hospital. An orientation phase introduces the MEDINET concept and systems approach to hospital management and staff personnel concerned with the application. This is followed by a site analysis phase to review hospital procedures, suggest changes, and arrange for equipment installation. A file development phase follows, in which necessary data are collected and assembled to form the particular data base for the application being installed. A training and file conversion phase prepares the hospital and concerned personnel for implementation. Actual conversion to the MEDINET system from prior operations varies between applications, usually involving some overlap for several days or week. Finally, a follow up phase assures the hospital management that the

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application has been successfully installed and is considered operational. MEDINET has approached the total hospital information system as a collection of application modules or subsystems, with early emphasis concentrated in the areas of hospital management. Each application is designed as a functional unit which can "stand alone,"-allowing subscriber hospitals to choose from a variety of applications; however, program interfaces are also provided so that applications can be linked together (i.e., data can be passed through from one application to the next) . Having established a "bottom up" design based upon accepted hospital applications, MEDINET expects to expand their system, as cost justification can be established, into all areas of the hospital and into medical data collection and reporting.

3. Medelco

Medelco Incorporated, a subsidiary of the Riley Corporation, designed their T*H*I*S (Total Hospital Information System ^(R)) as a dedicated hospital communications and data collection system. A special purpose central processing unit controlled by a Medelco furnished software system provides for a communications network of special card reader and teletype printer devices directly connected to the system. A unique edge-punched card is used to identify each hospital service which can be ordered through the system. The first Medelco system was installed in September 1967; since that time, a total of 24 T*H*I*S ^(R) systems have been placed into operation by hospitals ranging in size from 112 beds to over 900 beds. Medelco, Inc. recommends that a prospective hospital perform a detailed study of hospital departments to be included in the system, including their information needs and their present operating costs. An equipment configuration is then designed for the hospital based upon their specifications. Multiple files of special edge-punched cards representing the hospital's standard operating practices and chargeable services (i.e., medication orders, laboratory requisitions, purchase orders, etc.) are prepared and verified prior to delivery of the system. After installation of the central computer system a complement of card readers, teletype printer devices, and appropriate punched card

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files are placed in the various hospital departments. A complete staff-training and system-testing program is provided to insure proper system use. Typically, a card-maker unit is used by the admitting department to prepare a patient card for each admission. The admitting clerk places the patient card and the bed assignment card in a card reader, which reads the information and transmits it to the central computer. Special credit-card-sized patient cards are available for outpatient clinic use. The computer system maintains a perpetual patient location bed census file for real-time inquiry by physician, admitting office, business office, or information desk. The system also relays the patient location information to other affected departments such as dietary and housekeeping. Each transmission of information includes the date, time, and identification of the person sending the data. A special "Results Reporter" mark-sensing input station provides a means for the hospital laboratory to transmit test results back to the nursing floors; both the laboratory order and the test result include the time of entry to the system providing useful statistics on the elapsed time from request to result. The Medelco system is normally placed in a data output mode at midnight without affecting its communications and data collection ability [Page 100, lines 4-9, emphasis added]. The day's orders and service charges are summarized to a "Patient Ledger" or computer generated "Daily Billing Summary." Information can be formatted and recorded on an appropriate data file for subsequent processing by the hospital's patient billing system. Upon patient discharge, the business office has a patient invoice current through midnight; by inquiry to the system, any charges accumulated since midnight are printed on the teletype and can be added to the invoice to complete the billing. The Medelco system is oriented to data collection and rapid communication of orders throughout the hospital. The edge-punched card provides a simple means to catalog and enter the various hospital orders, services, and charges. A perpetual file of patient location and charge information is maintained; a 24-hour computer storage file maintenance run allows the system to purge itself of patient charge information on a routine scheduled basis without disturbing the bed census/patient location file. Special

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employee cards are available so that employees may "clock in" at their assigned work stations. Medelco provides for interfacing to other computer systems by formatting the data to an appropriate media (e.g.. magnetic tape or paper tape) ; this then becomes the input to various application programs such as patient billing, inventory control, and hospital statistics.

4. REACH

The REACH Corporation, a subsidiary of National Data Communications, Inc., has developed one of the most comprehensive hospital information systems commercially available. REACH, an acronym for Realtime Electronic Access Communications for Hospitals, is designed as a patient-oriented system supporting both medical and administrative information storage, retrieval, and processing. REACH utilizes a fast general purpose computer with special communications interface equipment connecting the central processor to a network of specially designed CRT (cathode ray tube) terminals. The CRT terminal is a unique feature of the REACH system; its design includes a badge reader which accepts a coded plastic card identifying the user to the system and allowing access to only that information defined by the code. The various user identification cards (e.g., nurse, physician, pharmacist, administrator, etc.) coupled with the terminal identifier code establishes authorized access to the REACH system and those system programs available to that user. A second unique feature is the use of 20 microswitch select buttons located on the left side of the CRT screen; these 20 buttons are associated with the 20 lines of information available on the CRT console. In a typical medication ordering sequence, a physician would place his personal badge in a REACH terminal and the system would respond with a list of his patients. He would then depress the appropriate "line select button" opposite the relevant patient's name. A "paging system" displays to the physician a selection of categories which would include, for example, medication orders. By depressing that select button, the doctor continues through a series of CRT displays providing drug name, dosage, and frequency of drug administration. Printer units supply a hard copy of the order where required (for example, in pharmacy, a

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printed gummed label is produced for use in dispensing the medication). The example medication order would normally be entered in 15 to 20 seconds. The REACH system maintains a complete computer patient chart reflecting all orders and services applicable to the patient during his hospitalization. Upon discharge, the patient chart is removed from the real-time system and recorded on magnetic tape for subsequent reference or use in statistical reporting. Charge information is also accumulated as patient orders are placed throughout the system, providing a running account for each patient. An extensive software system designed by the REACH technical staff controls the total operation of the computer and terminal network. A dual processor configuration is normally employed to provide for backup of the real-time process. The second computer functions as a batch processor when not needed for backup and is used to support the various application programs producing reports for hospital staff and management. Applications software supports a "Business Office Subsystem" including hospital billing, cost accounting, payroll function, purchasing and inventory function, outpatient accounting, accounts payable/ receivable, and general ledger. The "Patient Care Subsystem" contains application programs for admitting, patient transfer, service scheduling, dietary planning, laboratory test results recording and display, nurses' notes recording, physician orders, physician display function, and medical records maintenance. [emphasis added, page 101, lines 37-40].

The REACH Corporation began development of their system in early 1967 and installed the first test site system at the 275-bed Baptist Hospital, Beaumont, Texas. This configuration included 40 CRT nursing units, 2 in admitting, 3 in radiology, 2 in clinical laboratory, 5 in chartroom, 1 in pharmacy, 1 in doctors' lounge, and 10 in administrative offices). A second REACH system was installed in the 324-bed St. Francis Hospital, Miami Beach, Florida, in 1970. The initial configuration included 35 CRT consoles; however, after three months of REAH operation, the equipment configuration was increased both in

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storage capacity and by the addition of 15 CRT's. The REACH Corporation has signed contracts for three more systems, including their most recent agreement for a 625-bed hospital system. The REACH system is a major technological development in the application of computers and communications equipment to hospital operations. Supported by an extensive software executive programs, REACH provides a fast response, CRT-based order entry system. While early experience indicates a user reluctance to discard the "paper chart" in favor of the computer patient chart, the system does provide rapid electronic access to all hospital patient information including nurses' notes, laboratory results, standing orders, etc. (emphasis added, page 102, lines 16-18). Hard copy printout from the system provides a uniform record of the patient's stay for permanent storage in his chart.

5. Technicon

Technicon Medical Information Systems Corporation (formerly a division of Lockheed) initiated studies of hospital information needs in 1965. After three years of study by a physician /engineering team, a joint arrangement was established with the 440-bed El Camino Hospital, Mountain View, California, to develop an extensive medical information system. An additional three years of research and development activity produced the Technicon MIS-1 system. The MIS-1 system is based upon a central computer located in the Technicon facility with dedicated broad-band phone lines connecting this computer center to the hospital. The system uses a special CRT equipped with keyboard and light-pen for selection of its video screen: companion printers are used wherever pointed output is required. The system was designed for direct physician man/machine communications. The physician enters his identification number through the keyboard, and the MIS-1 system displays his list of patients in the hospital. Using the light-pen, the physician selects a patient's name, and a new display for that patient is furnished: he may wish to receive the computer-stored patient's chart (initiated upon

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the patient's admission to the hospital) before placing any orders. [Page 102, line 36-page 103, line 1, emphasis added]. The video display contains a Physician Master Guide, providing a list of functions or choices available to him. The physician might elect to review current orders for his patient as well as laboratory results before entering any new orders [Page 103, lines 2-4, emphasis added]. Basically, then, the physician is interacting with the MIS-1 system by using either or both light-pen selection and keyboard entry to indicate his requests for information stored in the computer and to place any medical orders appropriate for his patient. An extensive software system provides for the logical processes and terminal communications control required for MIS-1 to record the physician's order. The system automatically prints the new orders at the nurses' station for verification and signature. At the beginning of each work shift, the system initiates the printing of a Patient Care Plan for each hospital ward. Medications Due lists are printed for the nursing staff as both a reminder notice and a worksheet available for recording medication administration for subsequent entry by the nurse through the video terminal and for recording in the computer patient chart. MIS-1 terminals located in other hospital departments provide for both authorized data entry and inquiry of patient census, laboratory, radiology, pharmacy, dietary, and patient charge information. Each morning, a 24-Hour Summary by patient is printed, including cumulative medication, laboratory, and input/output reports. These summaries, coupled with an afternoon Interim Summary and manually prepared clinical reports (not entered in MIS-1 due to extensive narration or signatory requirements) , constitute the patient's medical chart for this hospitalization. In June 1971 , Technicon announced that a five-year operational service contract had been negotiated with El Camino Hospital. A complement of 48 CRT terminals and 28 printers were placed in the hospital, and system testing began in December 1971. During 1972, the MIS-I system was being phased into the hospital's operational functions of admitting, patient transfer, discharge, automatic charging, automatic cash posting, laboratory, radiology, EKG, EEG, dietary,

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inhalation therapy, physical medicine, and pharmacy, including unit dose medications [Page 103, lines 29-33, emphasis added]. Technicon projects that their NIIS-1 Regional Center system configuration should support an indefinite number of beds depending upon the number and size of central processing units utilized. The Department of Health, Education, and Welfare has awarded El Camino Hospital a study contract to produce a definitive evaluation of MIS-I. Columbus Laboratories of Battelle Memorial Institute will provide professional assistance in their extensive evaluation of the physician as a principal MIS-1 user, the effect of system costs vs. benefits in hospital operation and patient care, medical staff and hospital staff acceptance, and the potential of the system approach for supporting new trends (e.g., Health Maintenance Organizations) in health care organization and delivery. Technicon has also developed a Hospital Business Office Services applications system, which provides a comprehensive reporting system to subscriber hospitals in the areas of patient billing, accounts payable/receivable, payroll and personnel, general ledger, and inventory control.

6. MediData

In April 1966, representatives of three Charlotte, North Carolina, hospitals (Charlotte Memorial, Presbyterian, and Mercy) met to discuss the development of a shared-computer system based upon several design criteria which included: (1) direct involvement of hospital staff personnel in system definition; (2) improvement of patient care and hospital communications through a CRT terminal-based computer system; (3) use of ward clerks for data entry to conserve professional staff time; and (4) as a byproduct of system operation, production of the necessary administrative reporting (patient billing, accounting, general ledger, medical records statistics, etc.). In November 1966, MediData, Inc. was formed by the participating hospitals as a nonprofit corporation whose purpose was to provide the systems design and specifications for the planned shared-hospital computer system. Burroughs Corporation was selected to work with MediData, Inc., to furnish computer programming, data processing equipment, communications terminals, and a data center facility for on-going computer

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service support to the hospitals. The overall systems design consisted of two major segments: an on-line real-time processing system and an off-line batch processing system." To facilitate development and implementation, the program was defined in five phases: (1) off-line accounting, administrative and medical records system; (2) on-line reservations, admitting and surgery scheduling; (3) on-line doctor order entry and department requisitions; (4) on-line nursing care plans, medication plans, and service department results; and- (5) various departmental statistics, on-line nurses staffing, and doctor's office communications. Hospital nursing personnel and departmental coordinating committees worked directly with MediData in the early definition and design review activities to assure their participation and gain user confidence in the system as it was developed. The MediData/Burroughs system was first installed at the 876-bed Charlotte Memorial Hospital in June 1969 and became fully operational in October 1971. The system supports 85 hospital cathode ray tube (CRT) terminals and companion teletype printers connected to the Burroughs data..." (Page 84, line 31-page 104, last line).

Thus, Collen teaches: "The "Patient Care Subsystem" contains application programs for admitting, patient transfer, service scheduling, dietary planning, laboratory test results recording and display, nurses' notes recording, physician orders, physician display function, and medical records maintenance" (page 101, lines 37-40), and "the system does provide rapid electronic access to all hospital patient information including nurses' notes, laboratory results, standing orders, etc." (page 102, lines 16-18).

In addition Collen teaches: "Patient identification is best screened by comparing the data in the report with that contained within a computer-based Master Patient Identification File (MPIF). Such files typically contain a patient's hospital identification number, full name, birthdate, sex, and other data.

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Items of identification which are common to a report and the MPIF are compared and any inconsistencies are flagged." (Page 198, lines 4-9).

Collin added: "Screening of the remainder of the report depends on whether the information is coded or in natural language. [Page 198, lines 16-17, emphasis added]. Individual codes can be checked for validity and the overall completeness of the document evaluated. More sophisticated checking is also possible; for example, an analysis of a pattern of codes to determine the probability of descriptive findings being related to specific interpretations. This operation can be carried out in an interactive mode and may be of value in assisting the physician in developing his interpretation. Natural language data screening operations include checks of format, completeness, adherence to the rules of English grammar, and content analysis. No known general computer program provides automatic screening for either syntactic or semantic errors. It is practical, however, to confirm that each word in the text is correctly spelled. This is achieved by sorting the words contained in the incoming reports in alphabetical order. This alphabetical list is then matched against a computer-based master vocabulary. The procedure identifies new words and misspellings but not words which are correctly spelled but incorrect within context. A number of investigators have compiled medical vocabularies, and their scope is of interest. In the field of surgical pathology, one investigator [Gillette, Philip J.; Rathburn, Philip W.; and Wolfe, Harry B., Ph.D., "Hospitals Information System-Parts 1 and 2, *Hospitals J.A.H.A.*, 44 (1970)] found approximately 10,000 different words in the interpretation section of 110,712 surgical pathology reports. Another investigator [Bride, Edward J. "Minnesota Hospital State DP for Business Lab Work" *Computerworld*, November 17, 1971, p. 38 / Anthony, James M., Jr. "Data Processing in a Community of Hospitals." 50 (1969) / Smith, Robert M., "How to Automate a Hospital." *Management Sciences* (1966) 48-53] reported approximately 9,000 different words in scanning the same report section. An analysis of ten million words contained within a consolidated medical record file

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revealed 40,000 unique words, many of which were proper nouns [Anthony, James M., Jr. "Data Processing in a Community of Hospitals." 50 (1969)]. A study of the medical terminology contained in articles in the Journal of the American Medical Association over a one-year period revealed a total medical vocabulary of approximately 7,500 words. In contrast, a standard medical dictionary contains over 500,000 different terms. The limited size of operational medical vocabularies is unexpected but does greatly facilitate natural language data processing operations. It is not feasible to review the content of a natural language document to the extent possible with coded information ["The Patient Location Control System." *The Children Hospital Medical Center*, Public Relations Department / Barnett, Octo G., M.D., and Hoffman, Paul B."Computer Technology and Patient Care : Experiencies of a Hospital Research Effort." *Inquiry* 5 (1968) : 51-57] however, there are some practical data screening operations. One is to determine whether or not selected paragraph titles are followed by appropriate responses. The exactness of the check depends on the complexity of the data. For example, the identification information can be screened accurately whereas more descriptive information can only be checked for omissions and certain very obvious inconsistencies. More sophisticated analyses are theoretically possible by comparing the descriptions and interpretations with textbook information. (Page 199, lines 10-16, emphasis added).

D. REPORT COMPACTING

Each document record normally includes a label which identifies the document type, date, identification of the patient and author, indexing data, and the identification of internal sections of the document. The body of the document is stored as originally encoded in natural language or in a coded equivalent of natural language. Information which is coded at the time of entry has already been compacted and requires no further discussion. Natural language data may be handled in one of several ways (Page 199, lines 21-23, emphasis added). First, it may be retained in its original narrative format. No

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compacting step is required but it is difficult to search clear text and significant space is required for its storage. Second, blanks can be removed and each term preceded by a character count. The storage space is approximately the same as for clear text, but searching is facilitated by having identified the lengths of the terms. Third, each term may be replaced by a code word. This greatly compacts the text; for example, a 19-bit code can handle all the terms in a standard medical dictionary. The codes can be arranged to have a fixed relationship with computer word boundaries, facilitating highly efficient binary searching. That the codes can form the basis of a classification system is an additional advantage. The disadvantages are that a code table is required for conversion between natural language and the codes, and it is impractical to encode some items of information. With a large-sized vocabulary, the encoding/decoding process requires a significant amount of computer time. It is true, however, that the time is usually not critical because the volume of new document which must be processed each day is small, as is the information printed for most information retrieval operations. One method which may be used for circumventing the decoding process is to maintain separate files of both the original narrative text and its coded equivalent. In this system, searching is carried out using the coded file, but the information of interest is printed from the text file. The decoding step is eliminated, but there is the necessity for maintaining two separate files (Page 199, line 32-page 200, line 8]. There is no easy solution to the problem of encoding numeric values. It is obviously impractical to develop a coded equivalent for every possible number. There are two alternatives. One is to describe the number in natural language; for example, "one hundred" rather than "100." Second, the number may be retained in its original format but preceded by a special code and appropriate pointers to identify the beginning and end of a clear text numeric field. Another type of compacting is an actual reduction in the number of words in the original text. This is achieved by deleting "a," "the," and other terms which may not be essential to the meaning of a paragraph. Storage

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space is reduced, but there are the potential hazards of making the document less readable or of changing the sense of a sentence or paragraph.

E. DATA ABSTRACTING

Data abstracting is of value for generating subfiles or for transferring critical items of information to an integrated data base. These operations are facilitated when a classification system has been used for the interactive generation and storage of the report or for encoding the original natural language terms; however, limited abstracting is also feasible with clear text. For example, interpretation of malignant disease selected sections of reports can be automatically screened for a series of words and phrases which indicate a diagnostic. The abstracting of "significant" medical information is difficult with a coding scheme and almost impossible with natural language. The problem is that there are few clear-cut definitions of medically significant information and the data must usually be understood within context. This latter operation is particularly difficult to automate when processing natural language information.

F. FILE MAINTENANCE

On completion of the final editing, the reports are stored in one or more files. Three common files are: the document type file (e.g., pathology) ; an integrated patient data file; and special subfiles- (e.g., a tumor registry) . The items in the document label can be used as an index for inserting the new report into a file which is maintained in "sort sequence"; for example, a pathology file ordered by patient identification number and date. The techniques for adding the new information depend on whether sequential or direct access files are used. Magnetic tape or other sequential access files are updated by first sorting the incoming documents in the desired sequence. The resultant file is then merged with the original master, creating a new master. Direct access files which are maintained in sort order through use of index sequential or other techniques can be updated directly. Natural language

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vocabularies must be updated with the new words encountered in incoming reports. It is of value to maintain a current tabulation of the frequency of occurrence of each word as part of the vocabulary. Code tables must also be updated. A particularly complex updating process is the addition, modification, or deletion of information contained within a computer-based classification table. When a code is changed, appropriate modifications must be made to all codes to which linkages occur (Pages 2000-201, emphasis added).

G. INFORMATION RETRIEVAL

Retrieval of individual documents is easily achieved when they are stored on a direct access device and the label information is indexed in sort sequence. Options typically include the ability to locate documents by patient number, individual dates, or ranges of dates. Retrievals based on information contained within the body of a document involve sequential file searching, the nature of which is dependent on whether or not a coding/classification scheme has been employed.

1. Coded Data

The first step in searching a coded data base is locating the appropriate code numbers in a catalog. This may be done manually or through the use of an interactive terminal. Second, the logical associations of the information retrieval request are formulated. For example, report years 1970-1971, males over the age of 40, with a given series of interpretation codes and not others. The search strategy should permit scanning specific sections of the document, including the label, for items of information which have definite logical relationships.

2. Natural Language Data

Natural language reports, whether in clear text or a coded equivalent, are retrieved by locating a series of words or phrases which have the requested logical associations. (Page 291, bottom). A typical search request is entered by stating first which section of the document is to be scanned; for

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example, the microscopic findings or interpretation. The keywords or phrases are then entered.

Retrieval may be based on the location of a single word or one word in a series-the OR option. It is possible to specify that two or more words or phrases be located-the AND option. Any word or phrase may be made synonymous with any other word or phrase. A report may be retrieved only if it contains one or more words or phrases and not certain other words or phrases -the NOT option. This option is useful in reducing "false positives" which may result when words of interest are preceded by negatives.

Options may be required to control the degree of separation that is permitted between a group of words, all of which are to be located. Fixed order specifies that one word must directly follow another. This is useful in those instances in which there are two or more words which always occur together in a fixed sequence-for example, a phrase. The option may be modified so that one or more intervening words are permitted. When fixed order is not specified, any word order is accepted; however, the options can provide that the series of words to be located must occur together within the same phrase, sentence, or paragraph. It is important to be able to search for numeric data. One method of achieving this with natural language is to scan the text for numeric fields which appear adjacent to specific search arguments. When a numeric value is located, a comparison is made to determine if it is lower, equal, or higher than a specified value. Output options include the reproduction of one or more sections of the documents of interest or the generation of statistical tabulations.

3. Retrieval Problems

Finally, there is the problem of success of the information retrieval operations. Ideally, none of the desired reports should be missed nor should any documents be retrieved that fail to meet the search criteria. Such error-free operation is rarely achieved in practice for a number of reasons. Retrieval is dependent on the identification of a series of words or phrases that occur in some prescribed pattern. Reports will be missed if the requester fails to enter the appropriate search words or synonyms, if there are misspellings either in the data or in the request, or if search options are inappropriate to the

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data being scanned. The requester is required to have sufficient knowledge of the subject material so that he understands the ways in which the items of interest might be phrased. For example, if he is searching for a particular diagnostic impression, he must be aware of all the ways in which this might be stated (Pages 197-202)

Thus, Collen disclosed storing sentences and phrases related to medical data, inputting patient data, transferring the patient data to a server that tables the patient data, transferring the patient data to a report rendering component, and compiling sentences and paragraphs, by the report rendering component, from the stored sentences and phases and the tabled patient data.

In reference to appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the incorporation of the Collen teaching into Amado is supported for the fact that both references are in the medical field.

Thus, the combination of the Collen teaching with the Amado patent covers all the claims of this group and, consequently, the rejections should be sustained.

Group II (claims 28, 29, 40, 41, 46, 48-50, 52-54, 57, 59-61 and 63-65)

Appellants' states: "The rejection of each of the claims in Group II is based at least in part upon Official Notice. Applicants have previously requested citation of an actual reference in each instance in order to at least assess whether, in fact, the prior art suggests such a combination (as opposed to picking and choosing among elements known to exist in the prior art)." (Page 9, lines 2-5).

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The Examiner notes that the operations to edit a report in order to emphasize some contains using italics, headlines or bold are all and well known in the communication art, including the medical reports, as can be confirmed analyzing any of the following references:

ROSS Jr. et al., U.S. Patent No. 5,823,948, filed 7/8/96, Medical records, documentation and order entry systems (Col. 4, lines 6-10, col. 7, line 66-col. 8, line 11, and col. 15, lines 46-62);

~~PARKER et al., U.S. Patent No. 5,263,132, filed 9/38/90, Method for formulating documents using flexible design models providing controlled copyfit and typeface selection (Col. 2, lines 3-22, col. 3, lines 34-52, and col. 8, lines 39-47); and~~

HUTTENLOCHER et al., U.S. Patent No. 5,384,863, filed 1/24/95, Methods and apparatus for automatic modification of semantically significant portions of a document without document image decoding (Abstract, col. 9, line 67-col. 10, line 14, and col. 10, lines 42-53).

Therefore, it was obvious to one having ordinary skill in the communication art at the time the invention was made to include italics, headlines or bold in the reports of the Amado-Collen invention. One would have been motivated to use italics, headlines and bold to emphasize significant portions of a document.

Thus, the Examiner believes that the rejection of the claims of this group should be sustained.

Group III (claims 47 and 58)

Appellants' states: "Claims 47 and 48 are rejected based upon the combination of Amado, Collen's HCS, and Tallman et al. Tallman et al. is referenced for its teaching of "triage". However, rather than teaching the claimed "triage record" generation, Tallman et al. discloses a "triage encounter" and describes how to execute such an encounter. The combination of the cited references does not teach the creation of a triage record according to the recited steps set forth in the claims from which claims 47 and 58 depend." (Page 9, lines 11-16).

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The Examiner notes that Talman teaches: "The NMS nurse will connect the caller to a physician who works with the NMS system to complete the triager encounter.(Used when there exists a possible need for EMS Dispatch, but when a physician interview may identify more appropriate actions, i.e., cuts down on the "false positive" EMS Dispatches.)" (Col. 11, lines 29-34).

Tallman also discloses: "In an another aspect of the invention, a data processing system including a display utilizes a process for managing health care. A first series of questions is presented on the display to select one of a plurality of branched chain algorithms which assess the patient for an appropriate timing and level of medical care. A second series of questions is presented on the display to guide the patient through the selected one of the plurality of branched chain algorithms. Answers from the patient to the second series of questions are entered to the data processing system. A medical care timing and level of level care recommendation is made in response to patient answers to the second series of questions. In a further aspect of the invention, a data processing system includes a patient assessment stored program utilizing a plurality of branched chain logic algorithms. A stored program editor generates branched chain logic algorithms." (Col. 2, line 58-col. 3, line 6; emphasis added).

In addition, Tallman discloses a: "computer program for managing access to medical providers further includes a medical provider information stored program and said data processing system further includes a medical provider database, said computer program for managing access to medical providers further including: (k) software that links said patient assessment stored program and said patient database to said medical provider information stored program and said medical provider database with said clinical code and with patient information from said database when said patient assessment stored program and said medical stored program are executed on said data processing system." (Col. 78, lines 42-55; emphasis added).

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The assessment or triagers are stored in the patient database as the above quotations, and reported as show Fig. 7, in the Patient Problem/Nursing Assessment display. Thus, Tallman discloses patient records assessment or triages.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

PRK

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